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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,116	09/26/2001	Ekambar R. Kandimalla	HYZ-479CP (47508.577)	3956

7590

09/09/2003

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EXAMINER

EPPS FORD, JANET L

ART UNIT

PAPER NUMBER

1635

17

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/965,116

Applicant(s)

KANDIMALLA ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-8, drawn to immunostimulatory oligonucleotides comprising a dinucleotide of formula 5'-pyrimidine-purine-3' wherein pyrimidine is a non-natural pyrimidine, classified in class 424, subclass 184.1.
 - II. Claims 9-11, drawn to immunostimulatory oligonucleotide compounds comprising an immunostimulatory domain of formula II, classified in class 424, subclass 194.1.
 - III. Claims 12-19, drawn to an immunostimulatory oligonucleotide comprising a sequence of formula III, wherein said sequence comprises a potentiation domain and an immunostimulatory domain, and wherein Y is limited to a non-natural pyrimidine, classified in class 424, subclass 184.1.
 - IV. Claims 20-22, drawn to an immunostimulatory oligonucleotide compound comprising an immunostimulatory dinucleotide, a 3'-3' linkage and one or two accessible 5' ends, classified in class 424, subclass 184.1.
 - V. Claims 23-25, drawn to a method for modulating the immunostimulatory effect of an immunostimulatory oligonucleotide, classifiable in 536/25.3.
 - VI. Claims 26-38, drawn to a method for generating an immune response in a patient, or methods for treating a patient having a disease or condition, comprising administering an immunostimulatory oligonucleotide to said patient, classified in class 514, subclass 44.

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2. Inventions I-IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the immunostimulatory oligonucleotides according to Inventions I-IV can be used as an adjuvant, by combining the oligonucleotides according to Inventions I-IV with some other pharmacological agent to increase or aid in its efficacy by increasing the agent's antigenic response (see bridging paragraph between pages 3-4).
3. Inventions I-IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process according to invention V can be used to modulate the immunostimulatory effect of immunostimulatory oligonucleotides that are not set forth in inventions I-IV, for example the method of invention V can be used to modulate the effect of an oligonucleotide comprising a CpG dinucleotide, consisting of all naturally occurring pyrimidine and purine nucleosides (see page 2, lines 26-29), linked by phosphodiester bonds, and wherein said oligonucleotide is complementary to the gag or tat gene of HIV-1.
4. The methods of inventions V and VI are drawn to patentably distinct methods comprising different objectives, distinct method steps, and producing different effects.

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5. The products of inventions I-IV are drawn to patentably distinct products, having different structures and therefore requiring a separate search and separate consideration of the prior art.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group III, restriction for examination purposes as indicated is proper.

8. A telephone call was made to Wayne Keown on 9-5-03 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

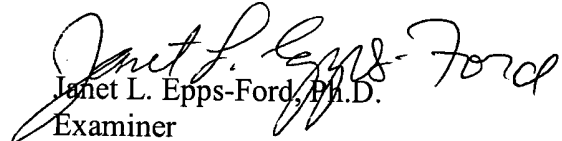
9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on Monday-Thursday, 8:30 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Janet L. Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE

September 5, 2003